

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP,
BI-LEVEL PAP, AND MECHANICAL
VENTILATOR PRODUCTS LITIGATION

Master Docket: No. 21-mc-1230

MDL No. 3014

THIS DOCUMENT RELATES TO:

All Actions Asserting Claims for Personal
Injury Brought by SoClean Users

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS HOLDING USA, INC.,
PHILIPS RS NORTH AMERICA LLC, and
PHILIPS RS NORTH AMERICA
HOLDING CORPORATION,

Defendants /
Third-Party Plaintiffs,

v.

SOCLEAN, INC. and
DW MANAGEMENT SERVICES, LLC,

Third-Party Defendants.

**PHILIPS DEFENDANTS'
THIRD-PARTY COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 14(a) and Pretrial Order No. 31, Defendants/Third-Party Plaintiffs Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC (“Philips RS”), and Philips RS North America Holding Corporation (collectively, “Third-Party Plaintiffs” or the “Philips Defendants”) bring this third-party complaint for contribution and indemnity against Third-Party Defendants SoClean, Inc. (“SoClean”) and DW Management Services, LLC (“DWHP”). Third-Party Plaintiffs’ allegations are based on knowledge as to themselves and, for the conduct of others, on information and belief following a reasonable inquiry.

INTRODUCTION

1. In this multidistrict litigation, certain individuals (the “Device User Plaintiffs”) have alleged they suffered a personal injury from their use of CPAP or BiPAP devices manufactured and recalled by Philips RS (the “Recalled Devices”). Device User Plaintiffs allege, *inter alia*, that the PE-PUR foam (a) breaks into particles that may then be inhaled or ingested by the Device User Plaintiff, and (b) emits certain volatile organic compounds (“VOCs”) when the foam degrades. Device User Plaintiffs have claimed pecuniary, non-pecuniary, and punitive damages for their alleged personal injuries.

2. The Philips Defendants maintain that the Device User Plaintiffs’ claims against the Philips Defendants are devoid of merit. Simply put, any emitted foam or any VOCs are well within long-established, and scientifically supported, safety levels.

3. Nonetheless, to avoid the uncertainty of litigation, and as announced on April 29, 2024, the Philips Defendants have entered into an agreement that would establish a \$1.075 billion settlement fund (“Settlement Fund”) to compensate eligible patients, *including eligible patients who used SoClean with their Recalled Devices*. In other words, the Philips Defendants are bearing

financial responsibility for those individuals’ alleged harms—harms which, if attributable to use of the Recalled Devices, were caused, in whole or in part, by SoClean’s devices through direct ozone inhalation, ozone’s contribution to foam degradation, and/or ozone’s contribution to the release of any associated VOCs from degraded foam. Thus, for those Device User Plaintiffs who also used one of SoClean’s devices with his or her Recalled Device, the Philips Defendants are entitled to contribution and indemnity from SoClean and the private equity firm that controls it, DWHP.

4. A meaningful percentage of Device User Plaintiffs used SoClean equipment to clean their CPAP/BiPap devices. Plaintiff Fact Sheets submitted under penalty of perjury in connection with this litigation indicate that *at least* 15% of Device User Plaintiffs are confirmed SoClean users. These self-declared SoClean users represent the absolute minimum number of Device User Plaintiffs that may have used SoClean because the number of Plaintiff Fact Sheets submitted to date is far lower than the total number of total Device User Plaintiffs. As of the date of this Third-Party Complaint, approximately 550 Plaintiff Fact Sheets have been filed, whereas there are more than 70,000 Device User Plaintiffs. The Plaintiff Fact Sheets and census data for this litigation establish that SoClean users resided in each state under the laws of which the Philips Defendants are seeking contribution.

5. SoClean and its private equity sponsor, DWHP, are notable for their recklessness or worse. SoClean, acting as DWHP’s alter ego, invited customers to use its devices with Philips RS devices by making multiple claims that its products were compatible with the CPAP/BiPAP products produced by Philips RS. SoClean manufactured and marketed its ozone-based cleaning devices (“SoClean Devices”)¹ as safe and effective for cleaning CPAP and BiPAP devices,

¹ SoClean models include the SoClean 1, the SoClean 2, the SoClean 2 Go, the SoClean 3, and the SoClean 3+.

including, by name, the devices manufactured by Philips RS (the “Philips Respironics PAPs”). SoClean also manufactured, marketed, and sold to consumers adaptors that SoClean designed to connect its ozone devices specifically to Philips Respironics PAPs

6. But in reality, SoClean Devices inject toxic ozone gas into the interiors of Philips Respironics PAPs and into the homes of Philips Respironics PAP users. The amount of ozone SoClean Devices release is substantial. Independent laboratory tests conducted in 2019 evidenced that SoClean Devices release ozone at a level that far exceeds federal limits. Measuring ozone at the end of a SoClean cleaning cycle, the testing found the ozone level was more than 500 times the regulatory limit.

7. Additionally, as evidenced by FDA testing, unsafe levels of ozone remain in the PAP tank, hose, and mask following the end of a cleaning cycle. PAP users can then inhale this residual ozone upon use of their PAP device.

8. Ozone poses a lengthy list of health problems including, *inter alia*, lung damage, worsened asthma and COPD, and compromised respiratory immunity—the same conditions alleged by Device User Plaintiffs to be caused by use of their Recalled Devices. *See, e.g.*, Master Complaint ¶ 22. FDA has warned users of reports from “patients experiencing cough, difficult breathing, nasal irritation, headaches, asthma attacks and other breathing complaints when ozone gas-based products were used to clean, sanitize or disinfect CPAP devices and accessories.”² Similarly, EPA cautions that exposure to even “relatively low amounts” of ozone can cause harm

² U.S. FOOD AND DRUG ADMIN., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (last visited Apr. 27, 2024).

to the human body.³ Just one use of a SoClean device emits more than 500 times the federal standard at the end of that cleaning cycle.

9. Not only do SoClean products expose users of Philips Respironics PAPs to a known toxic gas, SoClean's ozone attacks the foam in the Philips Respironics PAPs, causing or significantly exacerbating foam degradation. Independent third-party testing to date has demonstrated that ozone exposure dramatically accelerates the level of PE-PUR foam degradation. Independent testing also has demonstrated that ozone exposure results in elevated levels of VOC emissions. These are the same alleged injury causes (foam degradation, VOCs) being asserted against the Philips Defendants by the Device User Plaintiffs.

10. Philips RS has never endorsed the use of SoClean Devices to clean Philips Respironics PAPs. Instead, Philips RS has directed users in its User Manual to clean the device and tubing with "water and a mild liquid dish washing detergent." Further, FDA has indicated there is no reason to use ozone in connection with CPAP or BiPAP products, advising PAP users to "follow the cleaning instructions provided by the CPAP's manufacturer, which normally include regular cleaning with soap and water."⁴

11. For years, SoClean has known about the destructive properties of ozone, yet it hid the risks associated with its ozone-based devices. SoClean has acknowledged internally that its ozone cleaners [REDACTED] when injected into a PAP device; the only question was [REDACTED]. Yet SoClean neither disclosed nor attempted

³ U.S. ENV'T PROTECTION AGENCY, *Ozone Generators that are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims.,How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited Apr. 27, 2024).

⁴ See U.S. FOOD AND DRUG ADMIN., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (last visited Apr. 27, 2024).

to mitigate the risk of degradation, instead continuing to market its devices as safe and effective for use with PAP devices, including Philips Respironics PAPs.

12. To the extent the Philips Defendants are bearing or may in the future bear financial responsibility for any personal injury damages alleged by a Device User Plaintiff, *and* the Device User Plaintiff also used one of SoClean's devices with his or her Recalled Device, SoClean's negligent and intentionally misleading conduct will have contributed to those harms, making SoClean liable in contribution and indemnity for its relative culpability.

13. DWHP, SoClean's private-equity controller, is directly implicated in SoClean's faulty product design and ensuing negligent conduct. Through acquisition due diligence, DWHP—which esteems itself as specializing in healthcare sector investments—knew or should have known that: (i) exposure to ozone is toxic, (ii) the ozone in SoClean's devices was known to degrade the components of the very PAP devices SoClean designed them to clean, including Philips Respironics PAPs, and (iii) that SoClean was and continues to market, promote, and sell its devices without required FDA approval. Seeing these risks, DWHP left SoClean undercapitalized and underinsured while loading it with debt to DWHP's benefit. At the same time, DWHP treated SoClean as DWHP's alter ego, dominating SoClean's affairs without regard to the existence of SoClean as a separate corporate entity, while attempting to insulate itself from any exposure by fictitiously maintaining SoClean as a separate corporation on paper.

14. Impleading Third-Party Defendants will not prejudice SoClean, DWHP, or the Device User Plaintiffs given the current stage of the underlying litigation and the recent settlement agreement. On the other hand, Third-Party Plaintiffs will suffer prejudice if Third-Party Defendants are not impleaded into this action. As demonstrated throughout this pleading, there is substantial evidence that Third-Party Defendants are responsible, either in whole or at least in part,

for liability alleged by those Device User Plaintiffs who used SoClean Devices. And for all the reasons leading to the Court's entry of Pretrial Order No. 31, resolving Third-Party Defendants' liability in this proceeding will enhance judicial efficiency.

15. Third-Party Defendants' negligent and intentionally misleading conduct has contributed to the negligence claims for which the Philips Defendants are bearing or may in the future bear financial responsibility, making the Third-Party Defendants liable in contribution and indemnity for their relative culpability. The Philips Defendants therefore bring this Third-Party Complaint to ensure that, for any payment to a Device User Plaintiff who used a SoClean Device, Third-Party Defendants are held accountable for their contributory liability to Device User Plaintiffs' negligence claims.⁵

THE PARTIES

16. Third-Party Plaintiff Koninklijke Philips N.V. is a Dutch holding company with its principal place of business in Amsterdam, the Netherlands.

17. Third-Party Plaintiff Philips North America LLC is a Delaware company with its principal place of business in Andover, Massachusetts.

18. Third-Party Plaintiff Philips Holding USA, Inc., is a Delaware holding company with its principal place of business in Cambridge, Massachusetts.

19. Third-Party Plaintiff Philips RS North America LLC is a Delaware company headquartered in Pittsburgh, Pennsylvania.

⁵ The Philips Defendants reserve the right to seek contribution for any additional personal injury complaints arising in this matter, specifically, harms alleged in any Short Form Complaint for Personal Injuries where the Device User was a SoClean user.

20. Third-Party Plaintiff Philips RS North America Holding Corporation is a Delaware holding company with its principal place of business in Cambridge, Massachusetts.

21. Third-Party Defendant SoClean, Inc. is a Delaware corporation with its principal place of business in Peterborough, New Hampshire.

22. Third-Party Defendant DW Management Services, LLC, d/b/a DW Healthcare Partners is a Delaware company with its principal place of business in Park City, Utah. DWHP acquired a controlling interest in SoClean in December 2017.

JURISDICTION AND VENUE

23. This Court has supplemental jurisdiction over the subject matter of this complaint pursuant to 28 U.S.C. § 1367(a). The claims in this Third-Party Complaint are so related to and intertwined with the claims at issue in the remainder of the case, over which the Court has original jurisdiction under 28 U.S.C. § 1331, that they form part of the same “case or controversy” under Article III of the United States Constitution.

24. Because the claims asserted in this Third-Party Complaint are closely related to and intertwined with the claims in the main cases filed by Device User Plaintiffs against the Philips Defendants, venue is also proper in this Court for pretrial proceedings, and venue is proper in each of the courts in which Plaintiffs’ cases were originally filed. *See, e.g., O’Brian v. Allen*, 137 F. Supp. 691 (W.D. Pa. 1955) (“The provisions of Sec. 1391(a) have no application to a third-party defendant . . . [A] third-party proceeding is ancillary to the main action and the restrictions on venue do not apply to it.”). By asserting that venue is proper for the purposes of pretrial proceedings with respect to this Third-Party Complaint pursuant to 28 U.S.C. § 1407, the Philips Defendants do not waive their right to request that the cases filed against them be transferred back to the respective federal courts of origin for trial.

FACTUAL ALLEGATIONS

I. SoClean's Ozone-Based Cleaning Devices

25. PAP users must regularly clean their PAP device and accessories. PAP manufacturers, including Philips RS, recommend cleaning PAP devices with soap and water. SoClean has purported to offer a more convenient alternative that allows PAP users to “sanitize and disinfect your CPAP mask, hose, and reservoir without needing to take any pieces apart every day.”

26. According to SoClean, “SoClean is the dominant market leader for ozone cleaners, accounting for the vast majority of sales.”⁶ SoClean has marketed its devices as appropriate for use with all major brands of PAP devices, expressly including the Recalled Devices manufactured by Philips RS. SoClean has also manufactured and sold to consumers adapters that it specifically designed to make its ozone machines purportedly “compatible” with PAP devices, including PAP devices sold by Philips RS and Philips North America. SoClean, for example, created and posted on its website a compatibility chart that included Philips trademarks and identified multiple Philips Respironics PAP devices, including Recalled Devices, as “compatible with free adapter!” with SoClean products.⁷

27. SoClean continued to market its ozone-based devices as safe and effective for use with PAP devices even after repeated warnings from FDA that such claims were unsubstantiated and illegal. In 2019, for example, FDA told SoClean that [REDACTED]

[REDACTED]

⁶ Second Amended Complaint ¶ 245, *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 22-MC-00152-JFC (W.D. Pa. filed Oct. 10, 2022).

⁷ Internet Archive Wayback Machine, *CPAP Machine & SoClean Compatibility Chart / SoClean CPAP Cleaning Solutions*, <https://web.archive.org/web/20190621210744/https://www.soclean.com/support/soclean-support/soclean-compatibility/> (last visited Apr. 27, 2024, archived June 21, 2019).

including use with medical devices such as PAPs. FDA warned SoClean: [REDACTED]

[REDACTED]

[REDACTED]

28. Following SoClean’s failure to heed FDA’s repeated directives, FDA took its warnings public. In February 2020, FDA issued a Safety Communication informing patients and health care providers that devices claiming to clean, sanitize, or disinfect PAP devices or accessories using ozone “are not legally marketed for this use by FDA in the U.S., and as such, their safety and effectiveness for use with CPAP devices and accessories is unknown.”⁸

29. Undeterred, SoClean persisted with selling its devices for use “maintaining” PAP devices, but still instructing users to “clean” the product in the instructions, all in conflict with the FDA’s warnings. Finally, in November 2023, SoClean announced an “URGENT” “Medical Device” field correction relating to its SoClean 2 and SoClean 3 product models. As part of the field correction, SoClean informed users it was revising its labeling and instructions to include:

Additional clarity and consistency regarding that the SoClean2 and SoClean3 are not intended to replace CPAP manufacturers’ cleaning instructions but rather are to be used to supplement cleaning procedures for home use CPAP **masks and tubing**.

With each SoClean filter purchase, SoClean is supplying a complementary (no additional cost) Hose and Mask Adapter, **which facilitates use of the SoClean2 and SoClean3 equipment without ozone entering the CPAP**.⁹

⁸ See U.S. FOOD AND DRUG ADMIN., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (last visited Apr. 27, 2024).

⁹ SoClean, *URGENT Medical Field Correction*, www.soclean.com/field-correction (last visited Apr. 27, 2024) (emphasis added).

30. As admitted by SoClean, the recommendations were aimed at “reducing potential risks associated with the previous device design and labeling.”¹⁰

31. Tellingly, despite long knowing the potential harm its products posed, SoClean only disclosed these risks after being directed to do so by FDA. In SoClean’s draft Medical Device Field correction notice to consumers, SoClean claimed its provision of hose and mask adapters was driven by the fact that [REDACTED]

[REDACTED] Incredibly, FDA told SoClean this statement was misleading: [REDACTED]

32. Shortly thereafter, FDA issued its own Safety Communication regarding SoClean Devices, including additional information not provided in SoClean’s field correction. FDA took the opportunity to remind PAP users that SoClean’s devices were not in compliance with FDA regulations. It stated: “The FDA continues to work with SoClean to bring the firm into compliance with FDA requirements.”¹¹ FDA also reiterated harms associated with ozone. Specifically, FDA explained that “for ozone to be effective in destroying harmful bacteria [as marketed by SoClean], it must be present at a concentration above levels considered safe for humans.”¹²

33. For all the time before SoClean’s November 2023 field correction, SoClean allowed its ozone to reach the interiors of its users’ PAPs, as well as the air they breathed. SoClean in other words marketed and sold products with the potential to harm the very devices they would

¹⁰ *Id.*

¹¹ U.S. FOOD AND DRUG ADMIN., *Voluntary Recall of SoClean Equipment Intended for Use with CPAP Devices and Accessories: FDA Safety Communication* (Nov. 21, 2023), www.fda.gov/medical-devices/safety-communications/voluntary-recall-soclean-equipment-intended-use-cpap-devices-and-accessories-fda-safety (last visited Apr. 27, 2024).

¹² *Id.*

supposedly clean, as well as the human users of those devices, without any warnings of these foreseeable risks.

34. Even after FDA demanded that SoClean remove from its website and other promotional channels any statement that its products were intended for use with PAPs, SoClean ensured that U.S. consumers can still see SoClean's assertions that its products are meant to be used with Philips Respironics' PAPs. An online search for "SoClean" currently yields results containing compatibility claims expressly prohibited by FDA. For example, portions of the current SoClean.com website still provide the above-referenced compatibility chart and compatibility tool characterizing SoClean as compatible for use with Philips Respironics PAPs, including the DreamStation models. SoClean's site asks: "Is your SoClean Compatible?" The site then provides only two choices with respect to each pictured "Philips Respironics" model listed: "Compatible!" or "Compatible with free adapter!"¹³

35. Similarly, to this day, DWHP identifies and describes SoClean on its website's "our companies" page as creator of the "world's first automated CPAP cleaner and sanitizer."¹⁴

36. SoClean Devices function by generating ozone claimed to disinfect and sanitize surfaces.

37. Ozone consists of three oxygen atoms. As EPA explains, ozone "cleans" by shedding one of its three oxygen atoms, which bonds with the molecules of other substances,

¹³ SoClean, *CPAP Machine & SoClean Compatibility Chart / SoClean CPAP Cleaning Solutions*, www.soclean.com/uk/support/soclean-support/soclean-compatibility (last visited Apr. 27, 2024).

¹⁴ DW Healthcare Partners, *Our Companies*, www.dwhp.com/companies/#close (last visited Apr. 27, 2024) ("SoClean Inc. is the creator of the world's first automated CPAP cleaner and sanitizer, an innovative device that naturally sanitizes CPAP equipment.").

altering their chemical compositions.¹⁵ This reaction, known as oxidation, can kill viruses, bacteria, and odors. In relaying the dangers of using ozone-based products indoors, EPA stated, “[t]he same chemical properties that allow high concentrations of ozone to react with organic material outside the body give it the ability to react with similar organic material that makes up the body, and potentially cause harmful health consequences.”¹⁶

38. SoClean advises PAP users that cleaning with ozone for a [REDACTED]

[REDACTED] In its User Manual, SoClean recommends longer cleaning times than usual for PAP users in hot, humid environments, instructing them: [REDACTED]

[REDACTED] Accordingly, SoClean users in hot, humid environments expose their PAP devices to even higher levels of ozone if following SoClean’s instructions for use.

39. SoClean designed its devices to connect directly to the user’s PAP to circulate ozone through the PAP and its accessories. SoClean’s technology has remained relatively constant throughout its introduction of various product models, including the SoClean 1, SoClean 2, SoClean 2 Go, SoClean 3, and the SoClean 3+. By design, SoClean’s cleaning process floods the PAP tank, hose, and mask with ozone. As SoClean has described:

SoClean products generate and pump ozone through the supply tube and into the humidifier reservoir, cleaning not only the water, but also the inner walls of the reservoir. The ozone then moves through the CPAP hose, eliminating potentially harmful pathogens in the process. Ozone also passes in and out of the mask, cleaning it in the same manner as the hose and reservoir. When the short cleaning cycle is over, the ozone gas exits the

¹⁵ U.S. ENV’T PROTECTION AGENCY, *Ozone Generators that are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims.,How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited Apr. 27, 2024).

¹⁶ *Id.*

chamber through a special filter that converts it back into common oxygen.¹⁷

40. Omitted from this description are the facts that (i) when foam inside the PAP is exposed to ozone, ozone can cause the foam to degrade; and (ii) ozone can linger in the device and be breathed by the user, exposing the user to toxic gas.

II. Exposure to Ozone Causes Myriad Health Concerns

A. SoClean's Devices Exposed Users to Unsafe Levels of Ozone

41. As advised by EPA and FDA and incorporated into federal regulations mandating ozone limits for medical devices, “for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.”¹⁸

42. Among other harms, ozone can harm the respiratory system and permanently damage the lungs.

43. For people already in poor health (i.e., many of the individuals who may be prescribed CPAP and BiPAP devices), repeated exposure to ozone can increase the risk of dying.¹⁹ While people with chronic health conditions are particularly susceptible to ozone, ozone also can create health problems in otherwise healthy people.²⁰

¹⁷ Second Amended Complaint ¶ 58, *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 22-MC-00152-JFC (W.D. Pa. filed Oct. 10, 2022).

¹⁸ 21 C.F.R. § 801.415 (a).

¹⁹ CONN. DEP'T OF PUBLIC HEALTH, *Ozone Generators: What You Need to Know*, portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/environmental_health/eoha/pdf/ozoneneratorfactsheetpdf.pdf (last visited Apr. 27, 2024).

²⁰ U.S. ENV'T PROTECTION AGENCY, *Ozone Generators that are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims.,%20How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited Apr. 27, 2024).

44. Even low amounts of ozone exposure can result in coughing, throat irritation, shortness of breath, and chest pain.²¹ These symptoms can occur within minutes of even a single exposure.²²

45. Ozone worsens asthma, increases susceptibility to respiratory infections and compromises the body's ability to fight those infections, inflames lung tissue, and decreases lung function.²³

46. The federal regulation dictating maximum ozone levels for medical devices expressly recognize that inhalation of ozone can cause sufficient harm to the lungs to result in pulmonary edema, which can result in death.²⁴

47. In addition to a host of pulmonary-related issues, ozone exposure also causes other serious health conditions.

48. Federal regulations report the potential for ozone to result in "undesirable physiological effects on the central nervous system, heart, and vision."²⁵ For example, breathing ozone for even a short period can worsen symptoms in people with heart disease.²⁶

²¹ *Id.*

²² NY STATE DEP'T OF HEALTH, *Ozone Generators as Indoor Cleaners*, www.health.ny.gov/environmental/indoors/air/ozone_generating_air_cleaners.htm#:~:text=Ozone%20can%20react%20with%20other,health%20effect%20is%20less%20certain (last visited Apr. 27, 2024).

²³ U.S. ENV'T PROTECTION AGENCY, *Ozone Generators that are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims,,%20How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited Apr. 27, 2024).

²⁴ See 21 C.F.R. § 801.415 (b).

²⁵ *Id.*

²⁶ NY STATE DEP'T OF HEALTH, *Ozone Generators as Indoor Cleaners*, www.health.ny.gov/environmental/indoors/air/ozone_generating_air_cleaners.htm#:~:text=Ozone%20can%20react%20with%20other,health%20effect%20is%20less%20certain (last visited Apr. 27, 2024).

49. Ozone also can react with other chemicals in the air to produce additional chemicals and fine particles that cause, among other health conditions, further irritation to the eyes, nose, throat, and lungs.²⁷

50. Ozone increases the total number of VOCs in the air by combining with other common household chemicals to form “dangerous reaction products” that are inhaled.²⁸ As advised by the Connecticut Department of Health:

Ozone does not remove chemical contaminants from the air, but in fact, increases chemical air pollution by combining with chemicals typically found in the home, office, or school, such as ordinary household cleaners, plug-in type air fresheners, and personal hygiene products. Many of these products contain a class of volatile organic compounds (VOCs) called terpenes Ozone combines with terpenes to form dangerous reaction products (including formaldehyde, a known human carcinogen and respiratory tract irritant) which may be even more irritating than the parent chemicals.²⁹

51. Although recovery is possible from the harmful effects of short-term exposure to low levels of ozone, health effects are more serious and recovery less certain with higher levels or from longer exposures³⁰ such as the daily use recommended by SoClean.³⁰

52. SoClean Devices risk exposing PAP users to unsafe levels of ozone in two ways. First, ozone escapes from SoClean’s supposed “sealed,” “closed-loop system,” and vents into the

²⁷ See *id.*

²⁸ CONN. DEP’T OF PUBLIC HEALTH, *Ozone Generators: What You Need to Know*, portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/environmental_health/eoha/pdf/ozonegeneratorfactsheetpdf.pdf (last visited Apr. 27, 2024).

²⁹ *Id.*

³⁰ See U.S. ENV’T PROTECTION AGENCY, *Ozone Generators that are Sold as Air Cleaners*, www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims.,%20How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs (last visited Apr. 27, 2024).

PAP user's room where it can be inhaled.³¹ Second, and directly relevant to Device User Plaintiffs' alleged injuries, after a cleaning cycle is complete, some ozone remains in the PAP tank, hose, and mask, to be inhaled upon next use of their PAP device.

53. While SoClean claims a closed-loop system whereby ozone circulates within but does not exit the device, ozone can in fact leak into the surrounding environment. By design, PAP devices include an open pathway between its air intake (where the air enters the device to be pressurized before being gently pushed to the user) and its air outlet (where the PAP face mask and SoClean device connect to the PAP). Ozone that enters the PAP's air outlet travels through the open pathway and can escape through the air-intake opening.

54. Ozone leaks also can occur elsewhere, including through tubing connections and filters, allowing ozone to reach levels capable of harming the PAP user.

55. In addition to leaks, use of SoClean devices exposes PAP users to residual ozone that remains in the PAP tank, hose, and mask after completion of a cleaning cycle. The PAP user may unknowingly inhale this residual ozone after cleaning their PAP device.

56. In addition to leaks, use of SoClean Devices thereby exposes PAP users to residual ozone that remains in the PAP tank, hose, and mask after completion of a cleaning cycle. The PAP user may unknowingly inhale this residual ozone after cleaning their PAP device.

57. SoClean itself acknowledged these risks following a letter from FDA concerning

[REDACTED]

[REDACTED]

³¹ Ozone leaks can "occur at tubing connections, filters or through containers used to house CPAP accessories." Accordingly, FDA cautions users that "ozone gas in the nearby space may temporarily rise to unsafe levels, especially if the space is small or not well ventilated." U.S. FOOD AND DRUG ADMIN., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (last visited Apr. 27, 2024).

[REDACTED] In response, SoClean informed FDA in January 2019 that SoClean must update its labeling to [REDACTED]

[REDACTED]

[REDACTED]

58. SoClean’s actions to address these concerns on a go-forward basis do not undo any harm caused prior to these changes. SoClean’s negligent and intentionally misleading conduct has contributed to the harms alleged, making the Third-Party Defendants liable in contribution and indemnity for their relative culpability.

B. FDA and Third-Party Lab Testing Established Unsafe Levels of Ozone

59. Due to the health risks posed by ozone, medical devices that generate ozone must establish compliance with FDA regulations setting maximum acceptable levels of ozone.³² The law requires ozone output of indoor medical devices to be no more than 0.05 part per million (ppm) by volume of air.³³

60. In connection with FDA’s post-market safety concerns, FDA conducted lab testing of ozone-based cleaning devices, of which SoClean is the self-described “dominant” market supplier. As reported by FDA, the “testing demonstrated ozone-using disinfection devices generated ambient levels of ozone above limits considered safe for human exposure.”³⁴

³² See FDA’s Maximum Acceptable level of Ozone Rule, 21 C.F.R. § 801.415 (2019), which took effect in 1974. See FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

³³ 21 C.F.R. § 801.415(c).

³⁴ U.S. FOOD AND DRUG ADMIN., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or (last visited Apr. 27, 2024).

61. FDA testing evidenced that ozone levels in remained elevated PAP devices well after a cleaning cycle. Test results show that “ozone levels inside of the CPAP equipment can be above safe limits even several hours after cleaning is completed.”³⁵

62. In line with its test results, to date FDA has not approved or cleared for legal sale any ozone-based PAP cleaning device, including those manufactured by SoClean.

63. FDA is not alone in its findings that SoClean Devices exceed regulatory limits on ozone generation and release.

64. Earlier lab tests, conducted by Research Triangle Laboratories, were filed in federal court in a separate matter. The 2019 tests, requested by a manufacturer of UV-based PAP cleaners (as opposed to ozone-based), also show that SoClean Devices generate and release ozone substantially in excess of federal limits.³⁶ Upon the SoClean Device’s automatic shutoff at the end of the recommended cleaning cycle, ozone within the Teflon test chamber measured 28 ppm, or 560 times the regulatory limit. Another sample was collected following the recommended two-hour waiting period, and the ozone level measured 3.0 ppm—still 60 times greater than the levels deemed safe by FDA.³⁷

65. SoClean’s internal communications demonstrate its desire to hide the toxicity of the ozone and that its ozone levels—consistent with FDA’s and Research Triangle Laboratories’ test results—were dramatically in excess of regulatory limits. For example, in an email regarding SoClean’s Instructions for Use (IFU), SoClean’s Senior Director of Quality and Regulatory Affairs

³⁵ See U.S. FOOD AND DRUG ADMIN., *CPAP Machine Cleaning: Ozone, UV Light Products Are Not FDA Approved*, www.fda.gov/consumers/consumer-updates/cpap-machine-cleaning-ozone-uv-light-products-are-not-fda-approved (last visited Apr. 27, 2024).

³⁶ See Complaint, Ex. E, *3B Medical, Inc. v. SoClean, Inc.*, Case No. 1:19-cv-03545-KPF (S.D.N.Y. filed Apr. 22, 2019).

³⁷ *Id.*

stating, [REDACTED]
[REDACTED]
[REDACTED]

III. SoClean Devices Degrade PE-PUR Foam

66. Independent of the exposure of Philips RS' patients to a toxic gas, use by Philips RS' patients of SoClean's ozone-based cleaning devices accelerates and exacerbates the degradation of the PE-PUR foam in Philips' Respironics PAPs.

67. One mechanism of PE-PUR foam degradation is hydrolysis, the chemical breakdown of PE-PUR foam due to exposure to moisture and high temperatures. Under normal use conditions, hydrolysis is an extremely slow process that rarely occurs within the standard service life of a PAP device. In fact, the normal use conditions for the product call for the Philips RS Device being operated between 41° to 95° F temperatures. Hydrolysis, however, can be exacerbated when other stressors are introduced, e.g., exposure to ozone cleaning. Because ozone is such a strong oxidizer, its introduction to PE-PUR foam directly breaks certain chemical bonds present in the PE-PUR foam, which allows for the rapid acceleration of the hydrolysis process.

68. Ozone exposure as an acceleration and exacerbation factor for foam degradation has been corroborated by SoClean's internal documents, testing conducted by third-party laboratories, and the formal visual inspection conducted by Philips of its DreamStation 1 devices returned from the field.

A. SoClean's Own Documents Confirm SoClean Devices Have the Potential to Degrade PE-PUR Foam

69. SoClean has long known but kept secret that its ozone-based devices have the potential to damage the foam used inside PAP devices.

70. For years SoClean was aware of but kept secret the potential for harm, and actual harm, caused by ozone when used with various materials including foam and other materials found in PAP devices. SoClean deliberately concealed this knowledge. For example, results from a test of a SoClean Device with another manufacturer's medical device showed [REDACTED]

[REDACTED] In an email forwarding those results, a SoClean employee noted that the test [REDACTED]

[REDACTED] adding that [REDACTED]

[REDACTED]
[REDACTED]

(emphasis added.)

71. SoClean prepared a [REDACTED] based on a [REDACTED]

[REDACTED]

[REDACTED] The results of the review underscored SoClean's earlier findings: namely, that [REDACTED]

[REDACTED]

72. SoClean investigated degradation affecting sound-abatement foam inside ResMed PAPs (a competitor of Philips RS). SoClean's CEO informed employees, [REDACTED]

[REDACTED]

73. In April 2020, SoClean's Director of Engineering circulated a [REDACTED]

[REDACTED] report discussing potential messaging around ozone's

harmful impact on various materials. The document was based on internal testing of a device used to disinfect items like cell phones and keys. SoClean confirmed again in the report that ozone could degrade foam. The report listed a number of materials for which ozone had [REDACTED] [REDACTED] including foam. The report went on to consider consumer messaging based on the effects of these [REDACTED] cycles. Among the potential messaging options considered was the following guidance: [REDACTED]

74. A May 2020 external scientific publication circulated internally by SoClean's Director of Quality and Regulatory Affairs stating that polyurethane foam "does not exhibit good ozone compatibility."

75. In a November 2020 email between SoClean engineers regarding testing for the SoClean 3 device, one noted that FDA [REDACTED] [REDACTED] She then quoted an FDA comment that read, [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] (emphasis added.) SoClean never did so.

76. By mid-2023, FDA rebuked SoClean for its [REDACTED] submissions regarding product safety. Namely, in July 2023, FDA stated that [REDACTED]

[REDACTED]

[REDACTED] FDA urged SoClean to [REDACTED]

[REDACTED]

[REDACTED] Due to the inadequacy of SoClean's testing submissions, FDA reiterated an earlier request for SoClean to provide [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] underscoring that those devices [REDACTED]

To date, SoClean Devices remain without FDA clearance or approval.

77. SoClean has conducted additional testing regarding the impact of its products on Philips Respironics PAPs but, to date, has provided little in the way of those testing results in response to Third-Party Plaintiffs' discovery requests. SoClean, however, recently provided results for testing it conducted on another manufacturer's CPAP devices. The testing, performed in May 2019, evidenced that: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (emphasis added.) As noted above, SoClean advises that cleaning with ozone for a [REDACTED]

[REDACTED]

[REDACTED]

78. SoClean designed defective products and, even after knowing the harm those products posed to the very devices they were intended to clean, SoClean failed to warn PAP users about the potential risks of PE-PUR degradation and exposure to ozone. SoClean's negligent and intentionally misleading conduct has contributed to the harms alleged and for which the Philips Defendants are bearing or may in the future bear financial responsibility, making the Third-Party Defendants liable in contribution and indemnity for their relative culpability.

B. The Hawkins Phase I Study Showed that Ozone Exposure Dramatically Accelerates Foam Degradation

79. Following its voluntary recall, Philips RS retained multiple independent, certified laboratories to conduct various tests of its devices, including assessments of whether the use of an ozone-based cleaning device accelerates or exacerbates foam degradation within the Recalled Devices.

80. In early 2021, third-party consultant Scottsdale Scientific, LLC conducted an accelerated testing trial to study the impact of cleaning devices using ozone on the deterioration of foam (the "Hawkins Phase I Study"). For this study, samples of PE-PUR foam were exposed to a set of high temperatures and humidity levels for varying lengths of time. The impact of ozone was studied by subjecting half of the samples to ozone on a schedule matching typical use of an aftermarket cleaning device, while the others ("no-ozone") were kept in a normal room atmosphere. To measure the rate of foam degradation, the rate at which the foam lost its tensile strength was used as a proxy (i.e., the duration at which the foam's tensile strength is down to half of its starting value, or the "half-life" for short).

81. After comparing the half-life for tensile strength of the ozone group and the no-ozone group, the Hawkins Phase I Study concluded that [REDACTED]

[REDACTED]

C. Philips' Formal Visual Inspection of Field-Returned Devices Corroborates that Ozone Exposure Exacerbates Foam Degradation

82. Philips' visual inspection of PAP devices returned from the field provides further evidence that the use of ozone cleaning devices is a significant contributor to degradation.

83. To determine the prevalence of foam degradation, Philips performed a formal visual inspection on returned/used DreamStation 1 devices. The visual inspection was conducted according to a specific protocol as part of the repair process. For this assessment, the device is disassembled to permit access to the blower box (where the PE-PUR foam is located) and other parts of the device air path. The blower was also removed from the blower box to allow for full visual inspection. In addition, photographs were taken of the blower box with and without the blower for use in further assessing whether any visible degradation occurred and, if so, where any foam particles accumulated within the blower box.

84. Following the visual inspection process, Philips conducted data analyses of two groups of devices: devices for which the user reported no use of ozone cleaning, and devices for which the user reported use of ozone cleaning.

85. In the U.S., of the group of patients who reported no use of ozone cleaning, [REDACTED] of their returned devices showed no obvious visual foam degradation. By contrast, of the group of patients who reported use of ozone cleaning devices, [REDACTED] of their returned devices showed significant visual foam degradation. Therefore, devices for which the user self-reported ozone use were [REDACTED] more likely to have significant visual foam degradation than those where the user reported no ozone use.

D. Subsequent VOC Testing Further Evidences that Ozone Exposure Not Only Accelerates Foam Degradation, but also the Emission of VOCs

86. The observation from visual inspection is consistent with additional laboratory testing, which shows that DreamStation 1 devices exposed to increasing cycles of ozone cleaning had increasingly more severe visual degradation. Regarding VOCs, additional testing also shows that ozone exposure results in elevated levels of emission of VOCs.

87. In March 2023, third-party consultant Eurofins Materials Science Netherlands B.V. performed testing on Philips' DreamStation 1 devices (the "Eurofins Study"). Devices were tested for VOC and aldehydes release after 1,300 ozone cleaning cycles (each cycle simulating one night of use followed by ozone cleaning), with one control device that was not subjected to ozone cleaning.

88. The Eurofins Study concludes that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] After 1,300 cycles, emission of diethylene glycol (an indicator of foam degradation) of the group of devices exposed to ozone was over [REDACTED]

[REDACTED]³⁸

89. Testing and analysis related to the impact of ozone on foam degradation clearly evidence that the use of ozone cleaners significantly escalates foam degradation in the Recalled Devices.

³⁸ A subsequent June 2023 toxicological assessment performed by third-party consultant Exponent concludes that [REDACTED]

IV. DWHP's Domineering Management and Undercapitalization of SoClean

90. DWHP has exercised its ownership of SoClean to render SoClean its alter ego, controlling SoClean's business decisions, both large and small. DWHP ran SoClean to its own benefit, treating SoClean as its personal piggy bank. Ignoring the clear risks associated with SoClean's business, DWHP left SoClean undercapitalized and underinsured, attempting to insulate DWHP from any fallout by maintaining on paper the existence of SoClean as a separate corporate entity.

91. DWHP is a "healthcare-focused private equity firm." The front page of its website prominently features its sophistication in the sector: "We know healthcare."³⁹ According to its website, DWHP is run by "seasoned healthcare executives with more than 120 years of combined industry experience." And DWHP claims that its "investment focus allows us to better understand and monitor the *regulatory climate*, pending and current reimbursement issues, and *government policies* and trends that impact the healthcare marketplace."⁴⁰

92. Given DWHP's announced sophistication in healthcare and healthcare regulation, DWHP knew or should have known from even a basic level of diligence at the time of its SoClean acquisition that SoClean's ozone-based cleaning machines were not FDA approved or cleared for use with PAPs and therefore illegal to promote or sell for use with PAP devices. In other words, DWHP knew or should have known that SoClean's business and primary source of income was predicated on illegal conduct and could be subject to an enforcement action at any time. Further, DWHP knew or should have known from its diligence that ozone was known to degrade the components of the PAP devices they were meant to clean, further placing SoClean's

³⁹ DW Healthcare Partners, *DWHP Home*, www.dwhp.com/ (last visited Apr. 27, 2024).

⁴⁰ DW Healthcare Partners *Adding Value*, www.dwhp.com/adding-value/ (last visited Apr. 27, 2024) (emphases added).

business at risk. DWHP thus attempted to ensure this risk would only be to SoClean by maintaining SoClean on paper as a separate corporation with little capital.

93. Notwithstanding this risk profile, DWHP acquired a controlling interest in SoClean from SoClean's original shareholders, including its current management, for \$121 million on December 20, 2017.⁴¹ About \$86.5 million of this went to SoClean's former owners in cash, with another \$32.6 million in newly issued stock. Only \$1.6 million of the purchase price went to SoClean's working capital to operate the business. And the acquisition was accounted for on SoClean's balance sheet by dramatically increasing intangible assets and goodwill overnight, even though both were subject to immediate impairment because both were based on SoClean's illegal business. The accounting for the transaction created two sizeable new assets (i.e., intangible assets and goodwill) to draw down on SoClean's assets while loading the company up with debt. Overnight, with only \$1.6 million invested in SoClean's operations, SoClean supposedly increased dramatically in value. *See* SoClean Financial Statements attached as **Exhibit 1**. But those intangible assets and that goodwill were built upon the premise that SoClean had a viable and lawful business. And, when SoClean's auditors actually evaluated these assumptions, it required management to write down these assets.

94. Further, DWHP structured its acquisition in a manner that saddled SoClean with enormous debt that left SoClean in a precarious financial condition. DWHP financed its acquisition through a senior credit facility that imposed \$60 million in debt on SoClean, with liens on *all* of SoClean's assets and that of its parent. The creditor, White Oak Healthcare Finance,

⁴¹ *See* Complaint, *SoClean2 Pty Ltd v. SoClean, Inc.*, 4:18-cv-40054 (D. Mass filed Apr. 13, 2018); Answer, *id.* (D. Mass filed Oct. 2, 2018), ¶ 70 (SoClean admitting that "[o]n or about December 21, 2017, DW Healthcare, a Toronto-based private equity firm, acquired a **controlling interest** in [SoClean]") (emphasis added).

LLC, required that the \$60 million in financing be secured as senior debt because of SoClean's lack of liquidity, regulatory risk, and other material financial debts and obligations.

95. Less than a year after the acquisition, DWHP increased SoClean's debt by another \$33 million, also borrowed from White Oak Healthcare Finance. Again, the proceeds of this transaction were used to make distributions to SoClean's shareholders (i.e., to DWHP), not to improve the SoClean business, the safety of its products, or its financial position. More debt simply allowed more distributions to DWHP, thereby ensuring the quick recoupment of fully half of its investment, regardless of whether SoClean survived as a going concern. SoClean received no benefit from this distribution to DWHP; instead, it was only further saddled with 50% more debt, with no offsetting benefit. There was no reason for SoClean's board of directors, if operating independently from DWHP, to approve more debt just to turn over that amount to its private equity sponsor.

96. By December 2018, DWHP certainly had direct knowledge regarding SoClean's regulatory risks. On December 18, 2018, SoClean provided DWHP (and White Oak) a letter SoClean had received from FDA that day. The letter informed SoClean that [REDACTED] [REDACTED] Despite this risk, DWHP caused SoClean to take on additional debt, while once again attempting to insulate itself from any exposure.

97. In 2019, DWHP repeated its further leveraging of SoClean, this time by increasing SoClean's debt by another \$5 million, the proceeds from which were used to buy back shares of the company from SoClean's founder. Again, there was no reason for SoClean's board of directors to approve more debt and overleverage SoClean just to allow the repurchase of shares and enrich SoClean's former head.

98. DWHP did not only enrich itself through these distributions achieved by creating more leverage. DWHP further siphoned funds from SoClean, both in terms of management fees and the receipt of large dividends. DWHP secured annual management fees of about \$1 million, regardless of SoClean's performance. DWHP also dispersed to itself large dividends at the expense of SoClean. For example, the year following the assumption of the additional \$33 million of SoClean debt, DWHP paid itself and the other shareholders dividends of \$2.989 million.

99. In addition to DWHP's overt siphoning of funds, DWHP also obtained inadequate insurance coverage for SoClean. As a medical device company operating without FDA approval or clearance to sell its devices—devices that use a toxic gas to clean PAP devices that patients use every day³⁴ SoClean's business was fraught with regulatory and litigation risk. Despite this, DWHP opted for minimal insurance coverage for SoClean. For example, SoClean's insurer has informed SoClean its policy did not cover claims regarding, *inter alia*, SoClean's failure to disclose its devices emit ozone at levels declared unsafe by FDA. Worse still, even had the insurer deemed such claims was covered, SoClean's policy has an aggregate coverage limit of only \$10 million—clearly inadequate to cover a company of SoClean's risk profile.

100. In 2021, SoClean's house of cards began to collapse. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In 2021, SoClean wrote down its intangible assets and good will by a staggering \$38.6 million, a write-down over 100 times greater than its \$232,000 write-down the year prior.

101. SoClean has represented to this Court that it is under severe financial strain, such as by confirming as “accurate” descriptions of SoClean having “very attenuated . . . financial circumstances.”

102. Recognizing the risks associated with SoClean, DWHP hedged its bet by leaving the company undercapitalized and underinsured. Now, in the face of continued FDA scrutiny and FDA’s declination to grant SoClean regulatory approval or clearance, DWHP has threatened to pull the plug. As described to FDA in September 2023, [REDACTED]

[REDACTED]

[REDACTED]

103. DWHP has owned a controlling interest in SoClean since its acquisition of SoClean in 2017. As stated in SoClean Parent, L.P.’s Consolidated Financial Statement, [REDACTED]

[REDACTED]

[REDACTED]

104. Throughout its ownership, DHWP has dominated SoClean’s management and controlled it for its own benefit. As stated by the above Consolidated Financial Statement, SoClean’s Board of Managers [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] SoClean's Board of Managers meeting minutes show multiple DWHP personnel serving on the Board of Managers, with the Board chaired by DWHP founder and managing partner, Andrew Carragher. These executives serving on SoClean's board participate in SoClean's management beyond what is customary for an investor. In fact, SoClean's day-to-day management is run by DHWP, as DWHP admits by charging annually its \$1 million management fee.

105. [REDACTED]

[REDACTED]

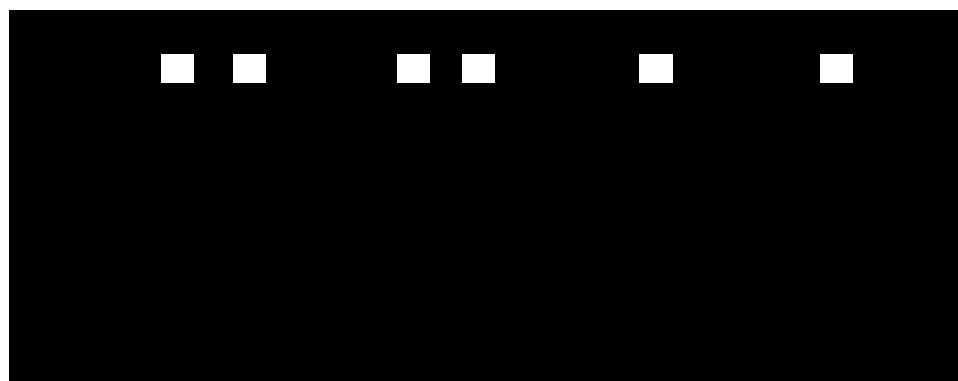
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

106. Preserving DWHP's ability to control SoClean is in line with DWHP's general investment philosophy. As described in a DWHP brochure:



107. Pursuant to its [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

108. DWHP's involvement in, running of, and control of SoClean's day-to-day affairs far exceeded that which is typical of or appropriate for a shareholder. DWHP controlled and was intimately involved in the minutiae of SoClean's operations. The limited produced records to date indicate that, at minimum: (i) DWHP was involved in and exercised authority over personnel decisions at SoClean; (ii) DWHP was involved in and exercised authority over branding decisions at SoClean; (iii) DWHP was involved in and exercised authority over testing and research decisions at SoClean; and (iv) DWHP was involved in and exercised authority over the marketing and advertising decisions at SoClean.

109. At all relevant times, DHWP knew or should have known through, *inter alia*, its heavy presence on SoClean's board and role in day-to-day management, that SoClean's flagship ozone machines were not FDA approved or cleared for use with PAPs, that SoClean's promotion and sale of its ozone-based PAP cleaning machines was unlawful and, thus, that nearly 100% of SoClean's revenues were derived from unlawful conduct. Similarly, at all relevant times, DHWP knew or should have known that exposure to the ozone used in SoClean's equipment is toxic, and that SoClean's equipment could cause foam within various PAP devices in the market, including the Recalled Devices, to degrade.

110. SoClean's conduct, as DWHP's alter ego, contributed to the harms alleged and for which the Philips Defendants are bearing or may in the future bear financial responsibility. Impleader is therefore appropriate.

CLAIMS FOR RELIEF

COUNT 1 – CONTRIBUTION

(AS 09.17.080(d); AK R RCP Rule 14(c))

111. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

112. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

113. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

114. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are also liable in proportion to their relative culpability.

115. The Philips Defendants are thus entitled to equitable apportionment from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 2 – CONTRIBUTION

(Ark. Code § 16-61-202, Ark. Code § 16-61-207)

116. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

117. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

118. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

119. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tortfeasors because the Philips Defendants and the Third-Party Defendants have several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in direct proportion their percentage of the fault.

120. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 3 – CONTRIBUTION
(Cal. Civ. Code §§ 1431 and 1432)

121. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

122. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro

rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

123. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants have joint and several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

124. The Philips Defendants are thus entitled to proportionate contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 4 – EQUITABLE INDEMNITY
(Cal. Code. Civ. Proc. § 428.10(b))

125. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

126. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

127. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability.

128. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are also equitably liable in proportion to their relative culpability.

129. The Philips Defendants are thus entitled to equitable apportionment from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 5 – CONTRIBUTION
(Colo. Rev. Stat. § 13-50.5-101 *et seq.*)

130. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

131. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.⁴²

COUNT 6 – CONTRIBUTION

(Del. Code tit. 10, § 6301, *et seq.*)

132. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

133. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

134. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

⁴² A contribution claim for Plaintiffs who do not participate in the Settlement Fund and who used SoClean is not yet ripe in this jurisdiction, but the Philip Defendants intend to bring such a contribution claim when actionable.

135. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

136. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 7 – CONTRIBUTION
(Washington, D.C.)

137. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

138. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

139. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tortfeasors and are also liable in proportion to their culpability.

140. The Philips Defendants are thus entitled to equitable apportionment from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 8 – CONTRIBUTION

(Haw. Rev. Stat. Ann. § 663-12, et seq.)

141. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

142. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

143. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

144. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of the common liability.

145. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 9 – CONTRIBUTION

(740 Ill. Comp. Stat. 100/0.01 *et seq.*)

146. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

147. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

148. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

149. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are subject to liability in tort arising out of the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

150. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 10 – CONTRIBUTION
(Iowa Code § 668.1 *et seq*)

151. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

152. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.⁴³

⁴³ A contribution claim for Plaintiffs who do not participate in the Settlement Fund and who used SoClean is not yet ripe in this jurisdiction, but the Philip Defendants intend to bring such a contribution claim when actionable.

COUNT 11 – CONTRIBUTION

(Maine)

153. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

154. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

155. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the damages. The Philips Defendants deny they are liable to Device User Plaintiffs.

156. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tort-feasors because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

157. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint tort-feasors.

COUNT 12 – CONTRIBUTION

(Md. Code §§ 3-1401, 3-1402, 3-1403, 3-1404, 3-1405, 3-1406, 3-1407, 3-1408)

158. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

159. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

160. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tort-feasors because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

161. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint tort-feasors.

COUNT 13 – CONTRIBUTION
(Mass. Gen. Laws ch. 231B, §§ 1-4)

162. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

163. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.⁴⁴

⁴⁴ A contribution claim for Plaintiffs who do not participate in the Settlement Fund and who used SoClean is not yet ripe in this jurisdiction, but the Philip Defendants intend to bring such a contribution claim when actionable.

COUNT 14 – CONTRIBUTION

(Minn. Stat. § 604.01 *et seq.*)

164. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

165. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

166. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their proportional share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

167. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants have common liability for Device User Plaintiffs' injuries, and Device User Plaintiffs could have brought an action against the Third-Party Defendants. As a result, the Third-Party Defendants are liable in proportion to their relative degrees of fault.

168. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 15 – CONTRIBUTION

(Mo. Rev. Stat. § 537.060)

169. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

170. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

171. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their proportional share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

172. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants have common liability for Device User Plaintiffs' injuries, and Device User Plaintiffs could have brought an action against the Third-Party Defendants. As a result, the Third-Party Defendants are liable in proportion to their relative degrees of fault.

173. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 16 – CONTRIBUTION
(Mont. Code §§ 27-1-703)

174. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

175. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

176. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tort-feasors because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

177. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint tort-feasors.

COUNT 17 – CONTRIBUTION
(Neb. Rev. Stat. § 25-21, 185.10)

178. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

179. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

180. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable, then the Third-Party Defendants have a common liability to Device User Plaintiffs, and the Philips Defendants may be, but should not be, required to pay more than its fair share of the common liability. As a result, the Third-Party Defendants are liable in proportion to their relative degrees of fault with respect to Device User Plaintiffs who used SoClean Devices. The Philips Defendants deny they are liable to Device User Plaintiffs.

181. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 18 – CONTRIBUTION

(Nev. Rev. Stat. §§ 17.225)

182. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

183. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

184. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their equitable share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

185. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tortfeasors because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

186. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint tortfeasors.

COUNT 19 – CONTRIBUTION

(N.J.S.A. 2A:53A-1; N.J.S.A. 2A:15-5.3, et seq.)

187. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

188. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

189. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of the liability.

190. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 20 – PROPORTIONAL INDEMNIFICATION
(New Mexico)

191. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

192. The Philips Defendants deny they are liable to Device User Plaintiffs. But if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the liability.

193. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, the Third-Party Defendants are liable for negligence. As a result, the Third-Party Defendants are liable for their pro rata share of the liability.

194. The Philips Defendants are thus entitled to indemnification from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.⁴⁵

COUNT 21 – CONTRIBUTION
(N.Y. C.P.L.R. § 1401, et seq.)

195. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

196. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their equitable share of the liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

197. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants subject to liability for damages for the same alleged personal injury or injury to property. As a result, the Third-Party Defendants are liable for their equitable share of the liability.

198. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 22 – CONTRIBUTION
(N.C. Gen. Stat. § 1B-1 *et seq.*)

199. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

⁴⁵ A proportional indemnification claim for Plaintiffs who do not participate in the Settlement Fund and who used SoClean is not yet ripe in this jurisdiction, but the Philip Defendants intend to bring such a contribution claim when actionable.

200. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

201. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

202. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

203. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 23 – CONTRIBUTION
(N.D. Cent. Code § 32-38-01 *et seq.*)

1. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

2. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

3. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

4. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative culpability.

5. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 24 – CONTRIBUTION
(Ohio Rev. Code § 2307.25)

6. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

7. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

8. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to

pay more than their proportionate share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

9. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly and severally liable in tort for the same alleged injury or loss to person or property. As a result, Third-Party Defendants are liable in proportion to their relative degree of legal responsibility.

10. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 25 – CONTRIBUTION
(12 Okla. Stat. § 832)

11. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

12. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

13. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

14. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants have joint or several liability in tort for the same

alleged injury to person or property. As a result, Third-Party Defendants are liable in proportion to their relative degree of fault.

15. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 26 – CONTRIBUTION
(42 Pa. Cons. Stat. § 8324, *et seq.*)

16. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

17. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

18. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than its proportional share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

19. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of the common liability.

20. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 27 – CONTRIBUTION

(R.I.G.I. § 10-6-3, *et seq.*)

21. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

22. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

23. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their proportional share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

24. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of liability.

25. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 28 – CONTRIBUTION

(S.C. Code Ann. § 15-38-20, *et seq.*)

26. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

27. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

28. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their pro rata share of the entire liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

29. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of liability.

30. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 29 – CONTRIBUTION
(S.D.C.L. § 15-8-12, et seq.)

31. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

32. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

33. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to

pay more than their pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

34. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their pro rata share of the common liability.

35. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 30 – CONTRIBUTION
(Tenn. Code Ann. § 29-11-102, et seq.)

36. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

37. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.⁴⁶

COUNT 31 – CONTRIBUTION
(Tex. Civ. Prac. & Rem. Code Ann. § 33.015, et seq.)

38. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

39. For those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay a percentage of the damages for which the Philips Defendants are jointly and severally liable greater than the Philips

⁴⁶ A contribution claim for Plaintiffs who do not participate in the Settlement Fund and who used SoClean is not yet ripe in this jurisdiction, but the Philip Defendants intend to bring such a contribution claim when actionable.

Defendants' percentage of responsibility. The Philips Defendants deny they are liable to Device User Plaintiffs.

40. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are jointly or severally liable in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for the percentage of the damages for which they are responsible.

41. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 32 – CONTRIBUTION
(Va. Code Ann. § 8.01-34, et seq.)

42. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

43. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

44. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by the Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than its pro rata share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

45. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint wrongdoers because the Philips Defendants and the Third-Party Defendants may have joint or several liability in tort for the same

alleged injury to person or property. As a result, the Third-Party Defendants are liable in proportion to their relative culpability.

46. The Philips Defendants are thus entitled to contribution from the Third-Party Defendants for all or part of any judgment entered against the Philips Defendants and to an allocation of fault as among all joint wrongdoers.

COUNT 33 – CONTRIBUTION
(Revised Code of Washington § 4.22.070)

47. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

48. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

49. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their proportionate share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

50. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are joint tortfeasors because the Philips Defendants and the Third-Party Defendants may have joint or several liability in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable in proportion to their relative culpability.

51. The Philips Defendants are thus entitled to contribution from the Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

COUNT 34 – CONTRIBUTION
(West Virginia Code § 55-7-13a - § 55-7-13d)

52. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

53. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

54. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their proportionate share of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

55. To the extent the Philips Defendants are found liable to the Device User Plaintiffs who used SoClean Devices, then the Third-Party Defendants are also liable because the Philips Defendants and the Third-Party Defendants may have several liability in tort for the same alleged injury to person or property. As a result, the Third-Party Defendants are liable for their comparative culpability.

56. The Philips Defendants are thus entitled to contribution from the Third-Party Defendants for their comparative share of any judgment entered against the Philips Defendants.

COUNT 35 – CONTRIBUTION
(Wisconsin)

57. The Philips Defendants incorporate each of the allegations above as if fully set forth herein.

58. The Philips Defendants request judgment against Third-Party Defendants for those amounts paid in the Settlement Fund by Philips in its discharge of the common liability to Plaintiffs opting into the Settlement Fund who used SoClean in excess of Philips' pro rata share.

59. Additionally, for those Device User Plaintiffs who do not participate in the Settlement Fund, if and to the extent the Philips Defendants are found liable for any damages alleged by Device User Plaintiffs, the Philips Defendants may be, but should not be, required to pay more than their just proportion of the common liability. The Philips Defendants deny they are liable to Device User Plaintiffs.

60. To the extent the Philips Defendants are found liable to Device User Plaintiffs who used SoClean Devices, the Third-Party Defendants are also negligent wrongdoers. As a result, the Third-Party Defendants are liable for their proportion of the common liability.

61. The Philips Defendants are thus entitled to contribution from Third-Party Defendants for all or part of any judgment entered against the Philips Defendants.

PRAYER FOR RELIEF

WHEREFORE, Third-Party Plaintiffs respectfully ask for:

- a. Entry of judgment in Third-Party Plaintiffs' favor against Third-Party Defendants;
- b. An award of contribution and indemnity proportional to the Third-Party Defendants' fault for all or part of any judgment for which Third-Party Plaintiffs are determined to be liable (if any), plus prejudgment and post-judgment interest;
- c. Reasonable attorneys' fees, costs, and expenses incurred in this litigation as allowed for the indemnity and other claims asserted by Third-Party Plaintiffs; and;
- d. Such other relief as the Court may deem appropriate and just.

JURY DEMAND

Third-Party Plaintiffs demand a jury trial on all issues so triable.

Respectfully submitted,

Dated: May 10, 2024

/s/ Erik T. Koons

Erik T. Koons (admitted *pro hac vice*)

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Philips Holding USA Inc., and Philips RS North
America Holding Corporation*

CERTIFICATE OF SERVICE

I hereby certify on this 10th day of May 2024, a true and correct copy of the foregoing was filed electronically and is available for viewing and downloading from the Court's ECF System. Notice of this filing will be sent to all counsel of record by operation of the ECF System.

/s/ Erik T. Koons
Erik T. Koons